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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,495	08/14/2006	Paolo Cerasoli	GRT/4865-90	4192

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NIXON & VANDERHYE, PC  
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ARLINGTON, VA 22203

EXAMINER
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VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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12/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/586,495	<b>Applicant(s)</b> CERASOLI, PAOLO	
	<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/20/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 29-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II & III, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/16/08.

Applicant's election with traverse of Group I claims 1-28 in the reply filed on 9/16/08 is acknowledged. The traversal is on the ground(s) that Figs. 3-7 do not show alternative embodiments. Examiner agrees with Applicant. However, claims 29-30 will not be examined because they are independent and distinct with Group I (claims 1-28) and there would be a serious search and examination burden. Please see the reasons of Election/Restriction mailed on 6/16/08.

The requirement is still deemed proper and is therefore made FINAL.

### ***Information Disclosure Statement***

The information disclosure statement filed 7/20/08 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Applicant should provide the copy of The Foreign Patent Documents 0947213 and 0715864.

### ***Specification***

1) This disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore, the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01 (o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP

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clearly states “Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...”. (Also see **MPEP 2181** (Rev. 1, Feb. 2000)).

Appropriate correction is required.

2) The disclosure is objected to because of the following informalities: the phrase on line 13, page 3 of Specification:”---and is defined in claim 1 and the succeeding claims” should be removed.

Appropriate correction is required.

### ***Claim Objections***

Claims 1-8, 14-15, 20, 22-23, 27 are objected to because of the following informalities: It is the Examiner’s position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant’s invention. Therefore, the Examiner has objected to the claims for the reason set forth above in the objection to the specification. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16, 18-20, 25-26, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Littmann (US 3,157,201).

Littmann discloses, Figs. 1-5, a device comprising: a container 24, 200 (as know that the valve element 200 is constructed in the same manner as the fluid exchange valve 15 described in Figs. 1-4) provided with a cover 26, 126; the container having a bottom, perimeter walls; an internal chamber 80; at

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least one connection 28-31 (Fig. 1-4), 101, 102, 204 (Fig. 5) extending from external lateral surface of the container; a rotating platform 23, 90, 99; a pin 21-22 integral with said rotating platform; an actuator 20 for rotation of said pin; at least one closing means 202, 402 having a pointed ended (Fig. 5); a receiving housing 103, 105 for holding the closing means 202, 402; an opening for passage of the closing means being fixed on the rotating platform with the opening turned towards the perimeter walls; a releasing housing 103 or 203; the closing means has undercut portions and is held spring loaded 403 radially inside the releasing housing; a means coupling to connection such as syringe or 404.

Claims 1-3, 7-9, 11-20, 25-26, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuson et al. (US 3,957,082).

Fuson discloses a container 20 provided with the cover 29; at least one connection 60; a rotating platform 47 (Fig. 3) a pin 45 integral with the rotating platform; an actuator 47 for rotating of the pin; at least one closing means 80; a receiving housing 37, 41; a releasing housing 39; an opening 55 for passage of the closing means being fixed on the rotating platform with the opening turned towards perimeter walls (Figs. 6-8); a reference marks 61, 63, 65, 67, 69, 71.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Littmann or Fuson in view of Folden (US 5,336,173).

Littmann or Fuson discloses the invention substantially as claimed. Littmann or Fuson does not suggest that the receiving or releasing housing contained disinfecting povidone gel; the connection with a fracture membrane.

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Folden suggests that the tube can be filled with a sterilizing iodine agent (povidone), col. 5, lines 22+); a scoring line 238 or fracture membrane to separate the tubes (Fig. 5).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Littmann or Fuson with disinfecting agent and fracture membrane, as taught by Folden, in order to prevent the growing of bacteria at the connection lines; and the purpose of provide a fracture membrane to separate the tubes easily.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Littmann or Fuson in view of Suzuki et al. (US 2004/0031756).

Littmann or Fuson discloses the invention substantially as claimed. Littmann or Fuson does not suggest that a visual means of indication of the number of cycles of dialysis.

Suzuki suggests that a dialysis apparatus comprising a visual means of indication of the number of cycles of dialysis (see Abstract and Fig. 12).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Littmann or Fuson with a visual indication, as taught by Suzuki, in order to recognize the number of the cycles of peritoneal dialysis.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763

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